

Patent Application Attorney's Docket No. 4430-57

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Yasmin WADIA and Scott Alan PRAHL

Serial No.:

09/686,594

Filed:

October 6, 2000

For:

BIOCOMPATIBLE DENATURED ALBUMIN LAMINA

AND METHOD

Box DAC Assistant Commissioner for Patents Crystal Park One, Suite 520 Washington, DC 20231 RECEIVED

JAN 2 4 2001

OFFICE OF PETITIONS

PETITION FOR FILING PATENT APPLICATION BY OTHER THAN ALL THE INVENTORS UNDER 37 C.F.R. 1.47(A)

Applicant, Scott Alan Prahl, hereby petitions the Assistant Commissioner to accept the filing of the above-identified U.S. Patent Application by other than all of the inventors.

Declarations are attached hereto providing proof of the pertinent facts concerning the refusal of a co-inventor to join in the present application for patent. The name and last known address of the co-inventor refusing to join in this application is as follows:

Yasmin Wadia, M.D. 8181 Fannin Street, #2537 Houston, Texas 77054

Counsel for Yasmin Wadia, M.D.:

C. Steven McDaniel McDaniel & Associates, P.C. P.O. Box 2244 Austin, Texas 78768

01/24/2001 AGDITOH 00000020 09686594

Attorney's Docket 4430-057

The invention was developed under the sponsorship of Providence Health System—Oregon ("Providence") by Scott Alan Prahl ("Prahl"), employee of Providence, and Yasmin Wadia ("Wadia"), a researcher under contract to Providence at all times relevant.

Prahl and Wadia have contractual obligations to assign their inventions to Providence.

Accordingly, Providence is entitled to clear title to the invention and to the above-identified patent application and any patent which issues thereon.

The U.S. Supreme Court, in *Solomon v. U.S.*, 137 U.S. 342, 346 (1890), held:

If one is employed to devise or perfect an instrument, or a means for accomplishing a prescribed result, he cannot, after successfully accomplishing the work for which he was employed, plead title thereto as against his employer. That which he has been employed and paid to accomplish becomes, when accomplished, the property of his employer. Whatever rights as an individual he may have had in and to his inventive powers, and that which they are able to accomplish, he has sold in advance to his employer.

It is clear that a contracted researcher who is paid to develop an invention comes within the scope of the language cited and is considered as an employee who has been paid in advance to develop the invention. *See In re Hobbs*, 136 U.S.P.Q. 489 (Atomic Energy Comm. Pat. Comp. Bd. 1963).

The Providence-Wadia research contract contains a provision requiring Wadia to assign to Providence all inventions, patent applications and patents issuing thereon arising within the scope of services provided under this contract. The subject matter of the present application was invented within such scope. Furthermore, the present application claims priority from U.S. Provisional Patent Application Serial No. 60/158,666, filed on October 8, 1999, which discloses the invention claimed in the present application. Wadia and Prahl jointly executed an assignment to Providence of the entire interest in the invention disclosed in that application.

Since Wadia was employed by Providence, that is, paid compensation to jointly develop, with Prahl the biocompatible albumin lamina and method, the invention belongs to Providence and each individual inventor who contributed to the development of the invention has a duty to jointly execute an application for patent covering the lamina and method and to assign the invention, patent application, and any patent which issues thereon to Providence.

In view of the refusal of co-inventor Wadia to execute the papers required for filing the present patent application, Prahl is believed to be entitled to make such application on behalf of and as agent for his co-inventor (Wadia). Providence, assignee of the entire interest and right in the subject matter of the present application, joins in this Petition.

Accordingly, filing of the application without Wadia's signature is requested.

The required fee pursuant to 37 C.F.R. 1.17(i) is enclosed.

20575

PATENT TRADEMARK OFFICE

Respectfully submitted.

MARGER JOHNSON & MCCOLL

11+11

Alexander C. Johnson, Jr. Reg. No. 29,396

MARGER JOHNSON & McCOLLOM, P.C. 1030 S.W. Morrison Street Portland, Oregon 97205 (503) 222-3613

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope

addressed to: Box DAC, Assistant Commissioner for Patents, Washington DC 20231 on Japuary /8, 2001.

Cianatura

OM. P.C.



/ DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled BIOCOMPATIBLE DEVALURED ALBUMIN LAMINA AND METHOD, the specification of which:

[x] was filed on October 6, 2000, as Application Serial No. 09/686,594.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: None

I hereby claim the benefit under Title 35, United States Code, Sec. 119(e) of any United States provisional application listed below:

Provisional Application No. Filing Date
60/158,666 Cotober 8, 1999

I hereby claim the benefit under Title 35, United States Code, Sec. 120 of any United States application(s), or Sec. 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, Sec. 112. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application: None

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Yasmin Wadia

Inventor's signature:

(Scott Alan Prahl, Ph.D.,

on behalf of Yasmin Wadia, M.D.)

Residence:

Houston, Texas

Citizenship:

India

Post Office address:

8181 Fannin Street, Apartment 2537

Houston, Texas 77054

Full name of second inventor:

Scott Alan Prahl

Inventor's signature:

Scott alan Krahl

//9/0/ (Date)

Residence:

Portland, Orégon

Citizenship:

United States

Post Office address:

4014 N.E. Knott

Portland, Oregon 97212

Assignee of Entire Right: Providence Health System-Oregon

Assignee's signature:

John V Fletcher, Director, Health Integration

ERVICES

State of Incorporation:

Oregon

Post Office address:

St. Vincent Hospital and Medical Center

9205 S.W. Barnes Road Portland, Oregon 97225

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Yasmin WADIA and Scott Alan PRAHL

Serial No.:

09/686,594

Filed:

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For: (JAN 2 3 2001 3 A

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Assistant Commissioner for Patents Crystal Park One, Suite 520 Washington, D.C. 20231 RECEIVED

JAN 9. 4 2001

Office of Petitions

DECLARATION OF JOHN V. FLETCHER

John V. Fletcher, being duly sworn, and having personal knowledge of the facts set forth herein, hereby deposes and says that:

- 1. I am Director of Health Integration Services for Providence Health System—Oregon ("Providence") of Portland, Oregon.
- 2. At all times relevant, Yasmin Wadia, M.D. ("Dr. Wadia") was under contract as a research fellow to Providence to provide services, including research, intellectual activity and/or technical services, in the development of biomedical laser-based coronary surgical procedures.
- 3. Pursuant to Dr. Wadia's fellowship, Dr. Wadia signed an Invention, Confidentiality, and Non-Disclosure Agreement ("Agreement"). See Petition Ex. D, Providence Health System Invention, Confidentiality, and Non-Disclosure Agreement. The Agreement includes a provision obligating Dr. Wadia to assign all rights in inventions, improvements, discoveries, works and ideas that result from work performed by Dr. Wadia for Providence. The Agreement further obligates Dr. Wadia to execute U.S. and foreign

patent applications and any other legal documents necessary to transfer title therein to Providence. See Petition Ex. D, \P 4.

- 4. Providence received an Invention Disclosure Form, titled "Technology for laser fusion of solid visceral organs (liver, spleen, and kidney)", on June 25, 1999 and jointly filed by Wadia and Scott Alan Prahl, Ph.D. ("Dr. Prahl"). See Petition Ex. A. In that Form, Drs. Wadia and Prahl listed themselves as co-inventors and as jointly conceiving of the invention.
- 5. Providence received an Invention Disclosure Form, titled "Denatured Albumin Lamina", on August 25, 1999 and jointly filed by Drs. Wadia and Prahl. *See Petition Ex. B.* In that Form, Drs. Wadia and Prahl listed themselves as co-inventors, as jointly conceiving the invention and jointly making the first written description of the invention.
- 6. The subject matter of the above-referenced Invention Disclosure Forms was the subject matter of U.S. Provisional Patent Application Serial No. 60/158,666, filed on October 8, 1999 and incorporated by reference. Co-inventors Wadia and Prahl jointly executed an assignment, *Petition Ex. C*, to Providence of the entire right and interest in the invention, application, and any resulting patent on October 14, 1999. The assignment was duly recorded in the U.S. Patent and Trademark Office on June 27, 2000 at Reel 010954/Frame 0821. *See Petition Ex. C*.
- 7. A Request for Filing a Provisional Patent Application and a copy of the Assignment were filed with the above-identified U.S. Provisional Application, of record in the present application. Drs. Wadia and Prahl named themselves as co-inventors in both of these documents.
- 8. Providence believes, based on the foregoing, that Drs. Wadia and Prahl are original, first and joint inventors of the invention disclosed in U.S. Provisional Patent

Application Serial No. 60/158,666 and claimed in U.S. Patent Application Serial No.

09/686,594.

9. Providence believes, based on the foregoing, that it holds legal and/or

equitable title to the entire interest and rights of the invention disclosed in U.S. Provisional

Patent Application Serial No. 60/158,666 and claimed in U.S. Patent Application Serial No.

09/686,594.

I hereby declare that all statements made herein of my own knowledge are true and

that all statements made on information and belief are believed to be true; and further that

these statements were made with the knowledge that willful false statements and the like so

made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code.

DATED this _____ day of January, 2001.

Respectfully submitted,

John V. Fletcher

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yasmin WADIA and Scott Alan PRAHL

Serial No .:

09/686,594

For: JAN 2 3 2001 E

October 6, 2000

BIOCOMPATIBLE DENATURED ALBUMIN LAMINA

AND METHOD

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Box DAC

Assistant Commissioner for Patents Crystal Park One, Suite 520 Washington, D.C. 20231 JAN 2 4 2001

OFFICE OF PETITIONS

DECLARATION OF SCOTT ALAN PRAHL

Scott Alan Prahl, being duly sworn, and having personal knowledge of the facts set forth herein, hereby deposes and says that:

- 1. I am employed as a Senior Research Scientist by Providence Health System—Oregon ("Providence") of Portland, Oregon, under an employment contract by which I am obligated to assign my interest in any invention I make or to which I contribute.
- 2. I am one of the inventors of the invention disclosed and claimed in the U.S. Patent Application referenced above.
- 3. Prior to November 1999, I developed and tested, jointly with Yasmin Wadia, M.D. ("Wadia"), a biocompatible albumin lamina and method for its use in repairing a lesion on a solid visceral organ.
- 4. Wadia and I jointly completed and filed an Invention Disclosure Form, titled "Technology for laser fusion of solid visceral organs (liver, spleen, and kidney)", on June 25, 1999. See Petition Ex. A. In that Form, Wadia and I listed ourselves as joint inventors and stated that we jointly conceived of the invention.

5. Wadia and I jointly completed and filed an Invention Disclosure Form, titled

"Denatured Albumin Lamina", on August 25, 1999. See Petition Ex. B. In that Form, Wadia

and I listed ourselves as joint inventors, and we stated that we jointly conceived of the

invention and jointly made a written description of the invention.

6. The subject matter of the above-referenced Invention Disclosure Forms was

the subject matter of U.S. Provisional Patent Application Serial No. 60/158,666, filed on

October 8, 1999. Wadia and I, as co-inventors, jointly executed to Providence an assignment,

Petition Ex. C, of the entire interest in the invention, application, and any resulting patent on

October 14, 1999. The assignment was duly recorded in the U.S. Patent and Trademark

Office on June 27, 2000 at Reel 010954/Frame 0821. See Petition Ex. C.

7. A Request for Filing a Provisional Patent Application was filed with the

above-identified U.S. Provisional Application and is of record in the present application.

Wadia and I are named as co-inventors in the Request.

8. Based on the foregoing, I believe that Wadia and I are co-inventors of the

subject matter disclosed in the present application, U.S. Patent Application Serial No.

09/686,594.

I hereby declare that all statements made herein of my own knowledge are true and

that all statements made on information and belief are believed to be true; and further that

these statements were made with the knowledge that willful false statements and the like so

made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code.

DATED this <u>9</u> day of January, 2001.

Respectfully submitted,

It alan Prahl

Scott Alan Prahl



PROVIDENCE HEALTH SYSTEM INVENTION DISCLOSURE FORM

1. Descriptive title:

Technlogy for laser fusion of solid visceral organs (liver, spleen and kidney)

Inventor(s):

a) First Name: Yasmin

Last Name: Wadia

Title: MD

Institution: Oregon Medical Laser Center, 9205 SW Barnes Rd, Portland, Oregon

Office Phone No: (503) 216 6828

Office Fax No: (503) 216 2422

Home Address: 380, NW Island Circle, Apt B-4 Beaverton, Oregon 97006 Home Phone No: (503) 690 8293 Citizenship: Indian

Nature of Involvement: Conception and practical surgical application. Contribution (%): 50 %

b) First Name:

Middle Name:

SCOTT

ALKN

Last Name PRAHL

Title: SR. RESEARCH SCIENTIST

Institution: ONLC

Office Phone No: (503) 216 2197 Office Fax NO: 503 216 -2412

Home Address: 4014 NE KNOTT

Home Phone No: (503) 289-4366 Citizenship: USA

Nature of Involvement: Conception and theory

Contribution (%):

3. Brief Description of the Invention:

Surgery of solid viceral organs like liver, kidney and spleen have always proved to be a challenge as these organs don't hold sutures well and are difficult to put back together after traumatic rupture. Elective removal of primary or secondary neoplastic lesions from the liver is rarely undertaken as it has a high morbidity and mortality associated with bleeding and biliary leakage and sensis.

Laser fusion of traumatic rupture of liver, spleen or kidney and /or fusion of large raw surfaces after partial non anatomical liver lobectomy can be achieved by the following technique. Viscous albumin (50-53 gm/100dl) solder mixed with indocyanin green dye (photo spectrometric analysis - 40-60 cm⁻¹) is spread thinly over the raw surface or into the ruptured edges which are then co-opted manually. A 805nm wave length diode laser is set at 10 Watts, with a pulse width & of .1sec and a pulse interval of .1 sec. The albumin -ICG solder is lazed over the target area using a visual feed back system. The next step involves harvesting native free omentum or using hetrograft omentum as the circumstances demand. The omentum is layered over the target surface

and the albumin -ICG solder is interspersed in a thin layer between the liver and omentum. The entire area is lazed till complete hemostasis is achieved.

4. Existing Documentation

a) Invention Records:

| Item | Conception | First Written Description or Flow Sheet | First Successful Operation/ Demonstration of Efficacy |
|--------------------------------------|-------------------------------------|---|---|
| Date | 04-15-99 | 04-19-99 | 04-21-99 |
| By Whom | Dr. Yasmin Wadia Dr. Scott Prahl | Dr. Yasmin Wadia | Dr. Yasmin Wadia Dr. Hua Xie |
| Where Recorded | Log book- Page-50 | Log Book-Page-50 | Log book- Page 51 |
| To Whom 1 st Disclosed | Dr. Hua Xie Dr. Gregory Kenton | Dr. Hua Xie Dr. Gregory Kenton | Dr. Hua Xie Dr. Gregory Kenton |
| Date First Disclosed | 04-19-99 | 04-19-99 | 04-21-99 |

b) Copies of pertinent documentation:

Log book pages 50 and 51.

5. Background: None available

| Patent | Inventor | Issued | Title |
|----------|----------|--------------|-------|
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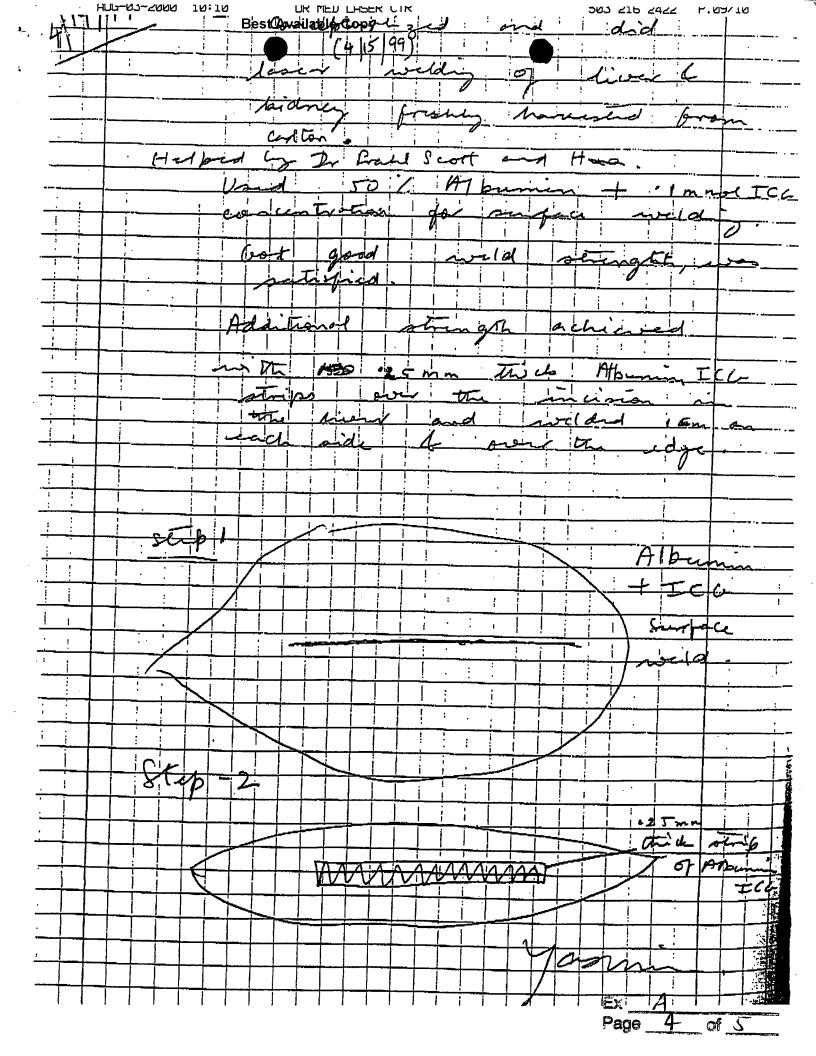
6. Advantages:

- 1) Trauma Surgery Can be used to fuse solid visceral organs and seal large raw surfaces with complete hemostasis without sutures in presence of complete coagulation failure.
- 2) Cancer Surgery Can be used to remove directly invading neoplasms, resect multiple primary or secondary discrete neoplasms which leave large irregular craters.
- 3) Living donor liver lobar transplants Will decrease the morbidity and increase the ease of doing living related liver lobar resection.
- 7. Disadvantages:

None

- 8. Detailed examples and/or drawings for making and using the invention:
- 9. Utility:
- 1) Life saving Quick trauma / battle field control of exsanguinating liver injuries.
- 2) Ellective Cancer surgery.
- 3) Living related Liver transplants.
- 10. Public Disclosure: None
- 11. Signatures (Inventor and Witnesses)

| VVENTORS _ | Scott 6 | hahl | 6-25-99 |
|------------|------------|------|---------|
| | yesin | | 6/25/99 |
| | Han | | 6425199 |
| | Lise A. B. | wlle | 4/25/99 |



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LASER FUSION OF LIVER AND SPLEENIC LACERATION - ACUTE FEASIBILITY STUDY

Date:

04-21-99

Type:

Acute Experiment - I

Animal ID:

Pig #997

Laser:

Diomed 25, 25W surgical diode laser, GaAIAs Laser Diode, wavelength 800nm

Surgeons:

Wadia/Kajitani

Assistants :

Laser scientist: Dr. Scott Prahl Kuong/Monica/Lisa

Anesthesia:

GA with ETT, Isoflurane.

Procedure:

After proper identification of the animal, anesthesia was induced with Telazole

8mg/Kg I/M. Isoflurane was given by face mask and the animal was intubated

with a size 5 F cuffed endotracheal tube.

The animal was used for another experiment and was utilized by us prior to

euthanasia.

The abdomen was opened using a right subcostal incision that was later extended across the midline and transversely onto the left side to facilitate exposure. The portahepatis was occluded using pringle's maneuver and the time was noted. Two liver lacerations were made one on the right lobe and one on the left lobe. A 5cm long and 3cm deep incision was made on the left lobe of the liver and the hepatic-portal sinuses (5-7mm in diameter) were exposed. An incision 3cm long and 1cm deep was made on the right lobe of the liver. The 800nm diomed-25W pulsed surgical laser was set at 10 Watts with 100msec pulses or 5 Hz (1Joule energy pulses / 5 times a second). Fifty- percent human albumin with . Immol of ICG was squirted into the incision. The edges were co-opted manually with finger pressure and lazing the liquid solder fused the incision. An ICG albumin solid solder .25mm thick wafer was layered over the surface of the liver 1cm on each side of the incision. The wafer was fused to the surface of the liver. The clamp on the portahepatis was released and the time noted.

An incision 3cm long and through 2/3 of the thickness of the spleen was made. Laser fusion similar to the method used above was used. After a brief waiting period of about 30 minutes the animal was sacrificed and the liver specimen was preserved in formalin and sent for histopathology. The spleen specimen was kept in saline and inspected the next morning for dehiscence.

Yasmin Wadia, M.D

| Ex _ | A | | |
|------|---|----|---|
| Page | 5 | of | j |

TOTAL P.10



1. Descriptive title
Denatured Albumin lamina

2. Inventor(s):



a) First Name: Yasmin

Last Name: Wadia

Title: Surgical Research Fellow

Institution: Oregon Medical Laser Center, 9205 SW Barnes Rd, Portland, Oregon Office Phone No: (503) 216 6828 Office Fax No: (503) 216 2422

Home Address: 380, NW Island Circle, Apt B-4 Beaverton, Oregon 97006 Home Phone No: (503) 690 8293 Citizenship: Indian

Nature of Involvement: Conception, preparation and practical surgical application.

Contribution (%): 50 %

b) First Name: Scott Middle Name: Alan Last Name: Prahl

Title: Sr. Research Scientist

Institution: Oregon Medical Laser Center, 9205 SW Barnes Rd, Portland, Oregon

Office Phone No: (503) 216 2197

Office Fax NO: (503) 216 2422

Home Address: 4014 NE Knott

Home Phone No: (503) 288 9366

Citizenship: USA

Nature of Involvement: Conception, practical application

Contribution (%): 50%

3. Brief Description of the Invention:

This invention is linked to 'Laser Fusion of solid visceral organs' patent. It is a new biomaterial which will be used as a temporary scaffold, in the same way that porcine omentum was utilized.

This biomaterial is made of a solid sheet of pure 47-57% denatured human albumin. The thickness of this material varies from 250µ to 2mm depending on the application. On gross examination, it looks a transparent amber sheet and on handling it, it is very pliable, contours easily and is insoluble in water. Its tensile strength would vary with its thickness and that parameter is still to be quantified.

The method for preparing is as follows:

Twenty five percent human albumin is dehydrated to a concentration of 47-57% (gm/100dl). A small quantity is interspersed between two plastic, teflon, glass or metal sheets that are mounted with specific distance spacers to produce the desired sheet thickness. This contraption is placed within a water -tight compartment that is then immersed in hot water maintained between 80-90 degrees centigrade for 1 minute. The denatured sheet is removed, double packaged and gamma sterilized.

| Ex | B | | | |
|------|---|----|----|--|
| Page | l | of | .3 | |

4. Existing Documentation

| a) Invention Recor | ds: | |
|--------------------|-----|--|
|--------------------|-----|--|

| Item | Conception | First Written Description or Flow Sheet | First Successful Operation/ Demonstration of Efficacy |
|-----------------------------------|------------------------------|---|---|
| Date | 08-24-99 | 08-25-99 | In- vitro laser fusion to the liver- 08-24-99 |
| By Whom | Yasmin Wadia, Scott Prahl | Yaşmin Wadia, Scott Prahl | Yasmin Wadia |
| Where Recorded | This disclosure | This disclosure | This disclosure |
| To Whom 1 st Disclosed | Lisa Buckley Hua Xie | This disclosure | Lisa Buckley Tim Denison |
| Date First Disclosed | 08-24-99 | 08-25-99 | 08-25-99 |

b) Copies of pertinent documentation:

5. Background

| Patent | Inventor | Issued | Title |
|-----------|-------------|------------------|---|
| 5,929,044 | Poppas | July 27, 1999 | Protein solder composition and method of use |
| 5,824,015 | Sawyer | Oct 20, 1998 | Method for Welding Biological tissue |
| 5,749,895 | Sawyer | May 12, 1998 | Method for bonding or fusion of biological tissue and material. |
| 5,552,452 | Khadem | Sept 3, 1996 | Organic tissue glue for closure of wounds |
| 5,209,776 | Bass, et al | May 11, 1993 | Tissue bonding and sealing composition and method of using the same |
| | | | |
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References:

 Small W 4th, Heredia NJ, et al. Dye-enhanced protein solders and patches in laser-assisted tissue welding. J clin Laser Med Surg 1997;15(5):205-8

2) Lauto A. Repair strength dependence on solder protein concentration: a study in laser tissue tissue welding.

| Ex_ | B | | | |
|------|---------|----|---|---|
| Page | <u></u> | of | 3 | - |

3) Lauto A, Poppas DP, et al. Solubility study of albumin solder for laser tissue welding. Laser surg Med 1998;23(5):258-62.

6. Advantages:

- Human albumin is completely biocompatible and is commercially available.
- Denatured albumin sheets are insoluble in water, transparent and pliable.
- They are easily sterilized and stored.
- They can be impregnated with a chromophore throughout or on the surface only.
- They can be impregnated with antibiotics if used in an infected situation.

7. Disadvantages:

No disadvantages have been discovered yet.

8. Detailed examples and/or drawings for making and using the invention: Refer patent and manuscript on Laser fusion of solid visceral organs.

9. Utility:

- Biomaterial scaffold for Laser Fusion of solid visceral organs.
- Can be used to make an air/water tight or hemostatic seal for suture line re-enforcement.
- Impregnated with antibiotics it can be used for temporary external integument replacement in burns or areas of extensive tissue loss.
- 10. Public Disclosure: None done.

| 1 | 1 | . Signatures | Anventor | and Witne | (pappa |
|---|---|--------------|----------|-----------|--------|
| | | | | | |

WITNESSES-

Scott Paulel

Scott Paulel

Muster Ray

Safeth or Confession

UNITED TES DEPARTMENT OF COMMERCE Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

PTAS

MARGER JOHNSON & MCCOLLOM, PC. ALEXANDER C. JOHNSON, JR. 1030 S.W. MORRISON STREET PORTLAND, OREGON 97205

101254220A



UNITED STATES PATENT AND TRADEMARK OFFICE NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 12/20/1999

REEL/FRAME: 010504/0702 NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

WADIA, YASMIN

DOC DATE: 10/14/1999

ASSIGNOR:

PRAHL, SCOTT ALAN

DOC DATE: 10/14/1999

ASSIGNEE:

SISTERS OF PROVIDENCE IN OREGON 520 PIKE STREET P.O. BOX 11038 SEATTLE, WASHINGTON 98111-9038

SERIAL NUMBER: 60158666

PATENT NUMBER:

FILING DATE: 10/08/1999

ISSUE DATE:

Ex C Page 1 of 6 010504/0702 PAGE 2

DIANE RUSSELE, PARALEGAL ASSIGNMENT DIVISION OFFICE OF PUBLIC RECORDS

> Ex <u>C</u> Page 2 of 6



PATENTS ONLY orney's Do. No. 4430-57



I HEREBY CERTIFY THAT THIS COR-

RESPONDENCE IS BEING DEPOSITED

WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN

TRADEMARKS, WASHINGTON D.C.

ASSISTANT COMMISSIONER FOR

PATENTS, WASHINGTON D.C. 20231 ASSISTANT COMMISSIONER FOR

TRADÉMARKS, 2900 CRYSTAL DRIVE,

ARLINGTON VA 22202-3513

ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND

1999 DEC 20 AM II: 37

OPR/FINANCE

In re application of: YASMIN WADIA and SCOTT ALAN PRAHL

Serial No. 60/158,666

Filed:

October 8, 1999

For:

LIVER REPAIR USING LASER SOLDERING

OF ALBUMIN IN A PORCINE MODEL

Box Assignment Commissioner of Patents and Trademarks Washington, D.C. 20231

Please record the attached original document or copy thereof and return the recorded instrument to the undersigned.

- 1. Name of party(ies) conveying an interest: (1) YASMIN WADIA, 380 N.W. Island Circle, Apartment B-4, Beaverton, Oregon 97006; (2) SCOTT ALAN PRAHL, 4014 N.E. Knott, Portland, Oregon 97212
- 2. Name and address of party(ies) receiving an interest: SISTERS OF PROVIDENCE IN OREGON, an Oregon Nonprofit Corporation, 520 Pike Street, P.O Box 11038, Seattle, Washington 98111-9038
- 3. Description of the interest conveyed: Assignment

Date of execution of attached document: October 14, 1999

- 4. Application number(s) or patent number(s). 60/158,666 Additional sheet attached? No
- 5. Name and address of party to whom correspondence concerning document should be mailed:

MARGER JOHNSON & McCOLLOM, P.C. 1030 S.W. Morrison Street Portland, Oregon 97205 Telephone: (503) 222-3613

- 6. Number of applications and patents involved: 1
- 7. Enclosed is our check for \$40.
- 8. Any deficiency or overpayment should be charged or credited to deposit account number 13-1703.
- 9. To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Customer No. 20575

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MARGER JOHNSON & McCOLLOM, P.C.

1030 S.W. Morrison Street Portland, Oregon 97205

Telephone: (503) 222-3613

Respectfully submitted,

MARGER JOHNSON & McCOLLOW, P.C.

Alexander C. Johnson, Jr.

Registration No. 29,396

Total number of pages comprising cover sheet and attached assignment: 4

ASSIGNMENT

Assignor:

YASMIN WADIA

380 N.W. Island Circle

Apartment B-4

Beaverton, Oregon 97006

COPY

SCOTT ALAN PRAHL

4014 N.E. Knott

Portland, Oregon 97212

Assignee:

SISTERS OF PROVIDENCE IN OREGON,

an Oregon Nonprofit Corporation,

520 Pike Street P.O Box 11038

Seattle, Washington 98111-9038

Title of

Invention:

LIVER REPAIR USING LASER SOLDERING

OF ALBUMIN IN A PORCINE MODEL

U.S. Patent Application:

Application Serial No.:

60/158,666

Filing Date:

October 8, 1999

For good and valuable consideration, the receipt of which is hereby acknowledged, the above-named Assignor hereby sells, assigns and transfers to Assignee, the full and exclusive right, title and interest in and to the above-identified invention, patent application and patent rights throughout the world, including foreign patent priority rights; said invention, application and letters patent in this or any foreign country, and all divisions, continuations, reissues and extensions thereof, to be held and enjoyed by Assignee, for its own use and benefit, and for its successors and assigns to the full end of the term for which letters patent may be granted in this or any foreign country, as fully and entirely as the same would have been held by Assignor had this assignment and sale not been made, and covenant that Assignor has full right so to do, and agree that Assignor will communicate to Assignee, or its successors and assigns, any facts known to Assignor respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, and do everything possible to aid Assignee, its successors and assigns to obtain and enforce proper patent protection for said invention in this or any foreign country.

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| Page | 4 | of | 6 | _ |

In the event that the patent application filing date or serial number is not known at the time this document is executed, Assignor hereby grants permission to the attorneys of record in the patent application to fill in the filing date and/or serial number above, and to record this assignment after such information is added.

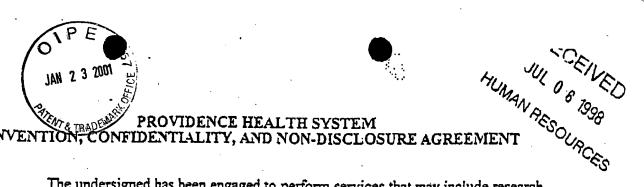
Executed at Portland, Oregon, this day of 1999. YASMIN WADIA Assignor STATE OF OREGON) County of Washington) Before me this 14 day of Ottober, 1999, personally appeared the above-named individual, to me known to be the person who is described in and who executed the foregoing assignment instrument and acknowledged to me that he executed the same of his own free will for the purpose therein expressed. OFFICIAL SEAL NOTARY PUBLIC - OREGON COMMISSION NO. 302938 Notary Public for Oregon MY COMMISSION EXPIRES JULY 14, 2001 My commission expires:

[SEAL]

Ex C
Page 5 of 6

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| 1999. | Executed at Portland, Oregon, the | nis 14 day of | OCTOBER 1999 |
| | | S. I d | lan Prull |
| | • | SCOTT ALAN I | |
| | | Assignor | |
| | | | |
| | E OF OREGON))ss. y of Washington) | | • • • • |
| the for | Before me this day of named individual, to me known to egoing assignment instrument and n free will for the purpose therein | o be the person who is I acknowledged to me | described in and who executed |
| | OFFICIAL SEAL SUZANNE M MYHRA NOTARY PUBLIC - OREGON COMMISSION NO. 302938 MY COMMISSION EXPIRES JULY 14, 2001 | Notary Public for My commission e | Oregon xpires: 7-14-01 |
| [SEAL |] | | |
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The undersigned has been engaged to perform services that may include research, intellectual activity and/or other technical services for the Sisters of Providence in Oregon dba Providence Health System ("Providence"), 1235 NE 47th, Portland, OR 97213. For the purpose of this agreement, persons "engaged" by Providence include but are not limited to, employees, students, contractors, collaborators, research assistants and/or research fellows. This agreement does not constitute an employment agreement and does not define any rights, obligations, or status of the undersigned in regards to Providence except for the intellectual property rights as set forth below.

In consideration of the undersigned's original and continuing engagement with Providence in a capacity in which he or she may produce or come into contact with proprietary information, the undersigned acknowledges Providence's ownership rights in such proprietary information and the need to safeguard the proprietary information from disclosure to competitors and others not engaged by Providence.

The undersigned therefore agrees as follows:

- 1. For purposes of this Agreement, "Proprietary Information" shall mean any information or material which is proprietary to Providence, or designated as Proprietary Information by Providence and not generally known by non-Providence personnel, to which the undersigned obtains knowledge or access as a result of the undersigned's relationship with Providence, including information conceived, originated, discovered or developed in whole or part by the undersigned. Proprietary Information includes, but is not limited to, the following forms of information, including technical information and other information of a similar nature (whether or not reduced to writing): discoveries, ideas, concepts, designs, drawings, specifications, techniques, computer flow charts and programs, models, data, documentation, diagrams, research, development, processes, procedures, "know-how", marketing techniques, past and prospective customers, cost data, pricing policies and financial information. Proprietary Information also includes any information described above which Providence obtains from another party and which is designated as Proprietary Information.
- 2. The undersigned shall turn over to Providence all originals and all copies of materials containing Proprietary Information in the undersigned's possession, custody or control upon request, or upon termination of the undersigned's engagement with Providence. The undersigned agrees to attend a termination interview with a manager of Providence to confirm turnover of such materials and to discuss any questions the undersigned may have about his or her continuing obligation under this agreement.
- 3. The undersigned shall, during his or her engagement by Providence and thereafter, hold in confidence and not disclose, communicate or transmit to unauthorized persons or use for unauthorized purposes any Proprietary Information.
- 4. Any inventions, improvements, discoveries, copyrightable works, or ideas conceived, developed or made by the undersigned in whole or in part during any term of his or her relationship with Providence, whether during business hours or otherwise, that relate to Providence's business, or that are made using any Providence equipment, facilities, materials, labor, money, time or other resources or that result from any work performed by the undersigned for Providence, shall belong exclusively to Providence and shall be deemed Proprietary Information for purposes of this Agreement. The undersigned agrees to communicate promptly to Providence any and all such inventions, improvements, discoveries, works and ideas and, upon

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request, to execute U.S. and foreign patent applications and any other legal documents necessary to transfer title therein to Providence, and to assist Providence in any proper manner in obtaining and enforcing intellectual property rights at Providence's expense.

- 5. Because of the unique nature of the Proprietary Information, the undersigned understands and agrees that if the undersigned fails to comply with any of his or her obligations under Sections 2, 3, or 4 above, monetary damages will be inadequate to completely compensate Providence for such breach. Accordingly, the undersigned agrees that Providence will, in addition to any other remedies available to it at law or in equity, be entitled to preliminary and permanent injunctive relief to enforce the terms of Sections 2, 3, or 4 above.
- 6. If any provision of this Agreement, or portion thereof, is determined to be invalid or unenforceable, the remaining provisions shall not be affected, and the Agreement shall be enforced as though the invalid or unenforceable provision, or portion thereof, were not in the Agreement.
- 7. This Agreement shall be governed by Oregon law. This Agreement contains the full and complete understanding of the parties with respect to the subject matter hereof and supersedes all prior representations and understandings, whether oral or written.
- 8. Should the undersigned wish to disclose any Proprietary Information for any purpose, he or she shall, at least 30 days prior to the date of the desired disclosure, submit a written request, stating the purpose of the disclosure, along with a copy of the Proprietary Information sought to be disclosed, to the Director of the appropriate research center. The Director, in his or her sole discretion, may authorize the disclosure of such Proprietary Information.

I have read, understand, and agree to the above terms and acknowledge receipt of a copy of this agreement.

| Date: | 98 SS# 541 - 49 - 5391 | | |
|--------------------|------------------------|----------|------|
| Signature: | yamin Warie | | • |
| Name (printed): _ | YASMIN. WADIA | : | |
| Mailing Address: _ | 9205 SW BARNES PERTS - | PORTLAND | • |
| | (OMLC) | OR-972 | 2 ,- |

Scott Prahl, PhD, Senior Research Scientist Oregon Medical Laser Center 9205 SW Barnes Rd, Portland, OR – 97225

Dear Scott,

Let me just get to the point and let the facts speak for themselves.

During the past two weeks I've come to realize that I erred when I included you as co-inventor on two of my patent disclosures, a) A Surgical Methods Patent – Laser Fusion of solid visceral organs and b) A biomaterial Patent – Denatured Albumin Lamina. At that time I did not understand inventor validation rules and did not have the information I now possess.

To state the facts and chain of events leading to the surgical methods patent – Laser Fusion of solid visceral organs.

- 1) The idea to use laser welding with albumin solder to repair liver, spleen or kidney was solely mine conceptualized on 04/15/99 and communicated to you and Dr. Xie. I did not invent laser welding technology, I just identified a possible application.
- 2) On 04/19/99 I did the first in-vitro experiment using 50% albumin solder mixed with 0.1mmol of ICG. This was witnessed by Dr. Gregory, Dr. Xie and David Spain. At this time I used a solid strip of Albumin-ICG as a scaffold. I used the Diomed laser, optimized the setting to 10 Watts with a pulse width of 100msec and a pulse interval of 100msecs giving an average power of 3.5 watts.
- 3) After the success of the bench top experiments I made up the a batch of albumin- ICG which was 50% albumin with ICG (photo spectrometric analysis 50 cm⁻¹).
- 4) I did a series of 18 acute liver repair experiments using laser welding from 04/21/99 to 06/24/99 and 5 acute kidney repair experiments using laser soldering from 05/11/99 to 05/21/99.

I therefore conceived and reduced to practice laser soldering to repair liver and kidney. I did not know that what I was doing was patentable, until Andrew Barofsky visited our lab and advised me to write a disclosure. I included your name as you were the senior laser scientist in the lab and I considered you a mentor and an important author on my paper.

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Regarding the facts relating to the biomaterial patent on denatured albumin.

I realized after my chronic experiments that I needed to develop a biomaterial to use as a scaffold in human beings as human omentum was very fatty and probably could not be used as a scaffold.

On 08/24/99 encouraged by you to try and make denatured albumin patches using solid 60-70% albumin solder as done by Karen MacNeally, I conceived and produced denatured albumin sheets using an entirely new method using 50% liquid albumin solder spread between two plastic sheets and denatured it in a water bath at 90 degrees centigrade for 1 minute. This method produced a transparent insoluble albumin sheet which varied from 89µm to 300µm in thickness. I wrote up the invention disclosure and included you as I regarded you as my mentor in this area.

During the last two weeks, I have realized that I made a mistake to confuse your role as a mentor as being a co-inventor for the above reasons. If you wish to contest the issue, be kind enough to spell out the reasons. We could then bring up the matter to Alex Johnson for arbitration and his legal council.

Yours truly,

Yasmin Wadia, MD

Cardiovascular Surgical Fellow

Oregon Medical Laser center.

Date-

12/6/99

Cc Dr. Kenton Gregory

Cc John Fletcher

Cc Rob Forest

Cc Alex Johnson

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| Page | 2 | of | 3 | |

YASMIN WADIA F 380 NW ISLAND CIR APT B4 BEAVERTON OR 97006-8530



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PORTLAND, DR - 97205

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Ex Page 3 of 3

YASMIN 380 NW BEAVER?

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Yasmin WADIA and Scott War PRAHL

RECEIVED

Serial No.:

09/686,594

JAN 2 4 2001

Filed:

October 6, 2000

OFFICE OF PETITIONS

For:

BIOCOMPATIBLE DENATURED ALBUMIN LAMINA

AND METHOD

DECLARATION OF ALEXANDER C. JOHNSON, JR.

Alexander C. Johnson, Jr., being duly sworn, and having personal knowledge of the facts set forth herein, hereby deposes and says that:

- 1. I am a principal of Marger Johnson & McCollom, P.C., a patent law firm.
- 2. I am an attorney of record for the U.S. Patent Application referenced above, as well as U.S. Provisional Patent Application Serial No. 60/158,666, filed on October 8, 1999, from which the present application claims priority and which is incorporated by reference, disclosing the invention claimed in the present application. I prepared and directed preparation of the provisional application based on written disclosures submitted jointly by Scott Alan Prahl, Ph.D. (Prahl) and Yasmin Wadia, M.D. (Wadia), see Petition Exs. A and B, and consultation with Prahl and Wadia jointly.
- 3. At the time of filing U.S. Provisional Patent Application Serial No. 60/158,666, I prepared an Assignment, *Petition Ex. C*, in favor of Providence Health System—Oregon ("Providence") of the entire interest in the invention, provisional application, and any resulting patent. The Assignment was jointly executed by Prahl and Wadia on October 14, 1999 and subsequently recorded in the U.S. Patent and Trademark Office on June 27, 2000 at Reel 010954/Frame 0821. *See Petition Ex. C*.
- 4. On or about December 7, 1999, I received from Wadia a copy of a letter from Wadia to Prahl. See Petition Ex. E. Despite naming herself and Prahl as co-inventors and

executing an Assignment to Providence in which she identified herself and Prahl as joint inventors, Wadia contests Prahl's designation as co-inventor in the original disclosures and declares herself sole inventor of the invention disclosed in U.S. Provisional Serial No. 60/158,666.

- 5. I directed preparation of the present application and accompanying formal papers including a Declaration of Inventors, Assignment and Power of Attorney. A complete copy of the application and formal papers were sent via first-class U.S. Mail to Wadia on October 18, 2000. A complete copy of the application and formal papers were sent via first-class U.S. Mail to Prahl on October 18, 2000. All of the relevant formal papers name Prahl and Wadia as co-inventors.
- 6. On November 6, 2000, I was contacted by C. Steven McDaniels ("McDaniels"), informing me that he represents Wadia. Under the Ethics rules, I could no longer deal directly with Wadia. On November 16, 2000, I sent via first-class U.S. Mail a letter to McDaniels, counsel for Wadia, requesting that Wadia appropriately sign and execute the formal papers and return them to me for filing in the present application. I specifically made clear that time was of the essence in this matter. In subsequent contact with McDaniels and in view of the urgency I had expressed, he made no assertion that his client had failed to receive the formal papers sent on October 18, 2000. McDaniels has indicated to me that Wadia will not sign the Declaration of Inventors, and she has not done so.
- 7. In view of Wadia's dispute as to joint inventorship of the invention disclosed in the provisional and non-provisional, the silence of McDaniel concerning receipt of formal papers, Wadia's failure to return executed papers to me for filing despite my urgent request for same, and McDaniels' indication that his client, Dr. Wadia, would not join in the application as submitted to her, I reasonably conclude that Wadia's conduct constitutes a refusal to join in the present application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

DATED this <u>l</u> day of January, 2001.

Respectfully submitted

Alexander C. Johnson, Jr.

MARGER JOHNSON & McCQLLOM, P.C.

1030 S.W. Morrison Street Portland, Oregon 97205 Telephone (503) 222-3613

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